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K970055

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

MAR - 5 1997

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document are accurate and complete to the best of KSEA's knowledge.

Applicant:

Karl Storz Endoscopy - America, Inc.
600 Corporate Pointe
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Contact:

Renate A. MacLaren, Ph.D.
Senior Regulatory Affairs Specialist

Device Identification:

Common Name

Shaver for Arthroscopy
Arthroscopic Shaver Blades

Trade Name

Karl Storz Multidrive Mini Shaver
Karl Storz Mini Shaver Blades

Indication: The Karl Storz Multidrive Mini Shaver and blades are designed to provide controlled shaving, abrading and cutting of bone and tissue during arthroscopic surgical procedures of the ankle, wrist, elbow and TMJ.

Device Description: The Karl Storz Multidrive Mini Shaver and blades are motorized surgical devices and include reusable and sterile, single use instruments. The instruments are long enough to gain access to the surgical area and are designed to be used as accessories to arthroscopes. The body contact materials of the blades are surgical grade stainless steel.

Substantial Equivalence: The Karl Storz Multidrive Mini Shaver and blades are substantially equivalent to the predicate devices since the basic features, design and intended uses are the same. The minor differences in design and dimensions between the Karl Storz Multidrive Mini shaver, blades and the predicate devices raise no new issues of safety and effectiveness, as these design differences have no effect on the performance, function or intended use of these devices.

Signed: _____

Renate A. MacLaren, Ph.D.
Senior Regulatory Affairs Specialist

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